

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12479



0 - FRONT

6064

12479-F

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service FOOD AND DRUG ADMINISTRATION COMPLAINT / INJURY REPORT				1. COMPLAINT NUMBER NWE-0934 / 12466-M	
				2. DATE OF COMPLAINT (Month / Day / Year) 07/08/97	
FORM OF COMPLAINT		a. (1) <input checked="" type="checkbox"/> TELEPHONE (2) <input checked="" type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT		4. SOURCE OF COMPLAINT	
5. COMPLAINANT IDENTIFICATION		a. NAME AND ADDRESS (Include ZIP Code) [REDACTED]		b. AREA CODE AND TELEPHONE NUMBER HOME ([REDACTED]) WORK ([REDACTED]) WIFE	
6. COMPLAINT OR INJURY 12479 12466		a. DESCRIPTION OF COMPLAINT / INJURY Purchased product by mail order. Both him & Wife used it for a couple of days, they experienced reactions to it. Wife: Shaking of hands, Rapid Heartbeat. Himself: Light headedness, Queasy stomach. Did not go to doctor. Read ingredients only one listed "MA-HUANG". Stopped taking product & returned to MFG.			
7. INJURY OR ILLNESS RESULTED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES * *(If "yes" complete items a through d)		a. EIB (HFC - 161) NOTIFIED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES DATE: _____		b. TYPE SYMPTOMS ONSET IHR. (1) <input type="checkbox"/> VOMITING (2) <input type="checkbox"/> NAUSEA (3) <input type="checkbox"/> DIARRHEA (4) <input type="checkbox"/> FEVER (5) <input type="checkbox"/> SKIN/EYE IRR. (6) <input type="checkbox"/> HEADACHE (7) <input checked="" type="checkbox"/> OTHER SEE 6a	
		c. ATTENDING HEALTH PROFESSIONAL (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "Yes" give name, address, phone number, and phone number)		d. HOSPITALIZATION REQUIRED? (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "Yes" give name, address, phone number, and phone number)	
8. PRODUCT AND LABELING		a. BRAND NAME THERMO-SLIM THERMO-GENESIS		b. PRODUCT NAME For Weight Loss Program	
		c. SIZE AND PACKAGE TYPE 1Bot.30/1Bot.60		d. NAME AND LOCATION OF STORE WHERE PURCHASED Dr. [REDACTED]	
		e. PACKAGE CODE / SERIAL NUMBER / ETC. NONE EXP. / USE BY DATE: NONE		f. DATE PURCHASED ?	
		g. PRODUCT USED (If "Yes" enter date) Date: ?		h. AMT. REMAINING NONE	
9. MANUFACTURER / DISTRIBUTOR OF PRODUCT		a. HOME DISTRICT ATL-DO		c. NAME AND LOCATION OF FIRM (Include ZIP Code) * Weight Loss Specialists (ON LABEL) P.O Box 1284 & P.O Box 7775 Northcross, GA 30091 * (SEE REMARKS)	
		b. C.F. NO. 1039855		d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES	
10. EVALUATION AND DISPOSITION		a. PROBLEM KEY WORD (1) CODE RX (2) DESCRIPTION MA-HUANG		c. DISPOSITION (1) <input type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F / U NEXT EI (3) <input type="checkbox"/> CLOSED WITHOUT FURTHER INVESTIGATION (4) <input type="checkbox"/> REFERRED TO OTHER FEDERAL AGENCY (Closes File) (5) <input type="checkbox"/> REFERRED TO STATE / LOCAL AGENCY (Closes File) (6) <input checked="" type="checkbox"/> REFERRED TO OTHER FDA ATL DISTRICT (7) <input type="checkbox"/> REFERRED TO OCI	
		b. EVALUATION (1) <input type="checkbox"/> NOT AN FDA OBLIGATION (2) <input type="checkbox"/> OBLIGATION, NO VIOLATION (3) <input checked="" type="checkbox"/> FDA ACTION INDICATED (4) <input type="checkbox"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE		11. PRODUCT CODE 54D--99	
				12. INFORMATION COPIES TO: <input type="checkbox"/> HFM-660 <input type="checkbox"/> HFZ-343 <input type="checkbox"/> HFD-730 <input checked="" type="checkbox"/> HFC-161 <input type="checkbox"/> HFV-210 <input checked="" type="checkbox"/> HFS-635 <input type="checkbox"/> OTHER	
13. REMARKS Tablets come in two colors yellow & red to be taken at different amounts daily Only listed ingredient is: Ma-Huang amount 2% for ea. tablet. Warnings are for people with illnesses, not for healthy consumers. See attached literature. Consumer called his Visa Records from Bank to get MFG name & address. * Universal Nutr. Corp., 5875 Peachtree, Ind. Blvd. #3., Norcross, GA 30092. MED-WATCH FORM SENT TO CONSUMER, TO FILL-OUT AND MAIL TO CENTER FOR DRUGS.					
14. NAME AND TITLE OF DISPOSITION OFFICIAL Lina Cicchetto, C/C/C/				15. DATE 07/09/97	